McKESSON

McKesson CSMP "Red Flags"

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McKesson CSMP has identified certain "red flags" that are indicators or areas of possible concern regarding shipments of controlled substances. Additionally, the "red flags" discussed herein are not intended to be all-inclusive as they can change over time depending on a variety of factors, e.g. new regulations, new drugs coming to market, or advancements in technology.

It is important to note that the "red flags" identified in this document are not always indicative of diversion. The facts and circumstances are often case specific and the various aspects of a customer's business model may provide an explanation or justification surrounding any possible "red flag(s)." Nevertheless, it is important that when "red flags" are identified they are reviewed to ensure appropriate due diligence.

This document is designed to separate "red flags" into two categories. The first section, "Apparent 'Red Flags'" lists those that are readily identifiable. The second section, "Non-Statistical 'Red Flags'" and "Statistical 'Red Flags'" provides a list of less obvious indicators that may need to be combined with other data or facts to draw out a "red flag" or determine if there is cause for concern.

Section I: Apparent "Red Flags"

Below is a list of examples of the more readily identifiable "red flags". These do not require expertise or extensive analysis in order to identify them. They would most likely be identified during an onsite visit to the customer's or prospective customer's place of business, during ordinary business meetings or discussions, or upon reviewing the customer questionnaire.

Physical Location

a) Security guards on premises.

b) Out-of-state patients and/or vehicles in parking lot, especially when the pharmacy is not located near a state line.

c) Long patient lines.

d) Lack of typical retail pharmacy front end merchandise or merchandise not consistent with a retail pharmacy practice.

e) Drug paraphernalia in the parking lot, e.g. drug syringes, empty prescription bottles.

f) Unusual signage, e.g. "Cash Only" or "We don't accept insurance".

g) No pharmacy signage or indication business is a pharmacy.

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h) Pharmacy is open outside of posted business hours.

Responses in the Customer Questionnaire

a) DEA registration information does not match the physical location of the customer's business.

b) Owner(s) have been previously convicted or charged with a felony and/or a crime related to controlled substances or fraud.

c) The pharmacist(s) or pharmacy tech(s) have been convicted of a felony drug or fraud offense.

d) One or more employees have prior disciplinary action(s) from State Board(s) related to fraud or controlled substances.

e) The pharmacy has had a DEA registration suspended, revoked, subject to a memorandum of agreement or other disciplinary action by DEA.

f) The pharmacy owner(s) has/have been subject to DEA issued disciplinary action regarding this location or any other location, or if a current know DEA investigation is pending.

g) The pharmacy has been previously disciplined by the State Board of Pharmacy or State Controlled Substance Authority or has a pending action before either regulatory agency.

h) Any pharmacist currently employed at the pharmacy was previously disciplined by the State Board of Pharmacy or other regulatory agency within the past 10 years.

i) A previous wholesaler or manufacturer ceased selling controlled substances to the pharmacy within past five years.

j) A previous wholesaler or manufacturer ceased selling controlled substances or restricted purchases of controlled substances to another pharmacy that was owned or is owned by the owner(s) of the current pharmacy.

k) The pharmacy employs someone who has been convicted of a felony offense related to controlled substances or who, at any time, had an application for a DEA registration denied, had a DEA registration revoked, or voluntarily surrendered a DEA registration for cause.

l) The pharmacy regularly fills for out of state providers.

m) The pharmacy's primary business model involves filling prescriptions for or dispensing directly to pain clinics.

n) High volume of cash business. **Note**: Focus should be given to the volume of cash business that is related specifically to controlled substances.

o) Pharmacy does not accept insurance.

p) Pharmacy owner, Pharmacist in Charge, or other pharmacy employees communicate a disregard towards prescription drug diversion and abuse.

q) The pharmacy's business model centers on controlled substances or the pharmacy is planning to expand its controlled substance business.

r) Pharmacy staff does not use or refuses to use the state's PDMP. (**Note**: As of December 2014, every state has a Prescription Drug Monitoring Program except Missouri. Missouri does have legislation pending. Additionally, the District of Columbia has passed legislation, but does not have an operational PDMP).[1]

Open Source Information

The term "open source" refers to information that can be derived from an array of publicly available resources. These resources can include media outlets such as newspapers, magazines, television, and radio; information from government sources such as agency web sites, governmental reports and press releases; and information from the internet in general. Open source information can even be discovered during the course of a conversation with others.

a) Information that a law enforcement or regulatory agency visited or raided the customer's or potential customer's place of business.

b) Adverse information from news reports, articles, or the internet regarding the customer, its owner(s) or employees.

[1] Information regarding various States' Prescription Monitoring Programs can be obtained from the National Alliance of Model State Drug Laws (NAMSDL) at www.NAMSDL.org. (Accessed March 25, 2015).

Section II: Detailed "Red Flags"

This section covers both Non-Statistical Red Flags and Statistical Red Flags. The examples contained herein are less obvious than those contained in Section I. They may require a triggering event, a new diversion trend/scheme, or additional facts or analyses to identify or determine their existence. Additionally, they may need to be combined with other data or facts to determine the significance or level of concern. As such, these are more likely to be identified by Regulatory Affairs, although the Sales and Operations teams should be familiar with these red flags to the extent they learn of them through the ordinary course of their business interactions with customers.

Non-Statistical "Red Flags"

1. Geographic Location

   a) The pharmacy located in a geographic area known or suspected of having higher than normal prescription drug diversion or level of prescribing.[2] This would include areas where diversion schemes are known to be centrally located. (Previous examples of this included the concentration of rogue internet pharmacies in Florida and the concentration of "pill mills" in Florida.)

   b) Customer is routinely filling prescriptions for controls for patients that reside outside of a reasonable or justifiable radius from the pharmacy, e.g., more than 10 – 15 miles. **Note**: It may, however, be justifiable for a pharmacy to fill for patients that reside farther away particularly if the pharmacy is located in a rural or isolated area or there are a limited number of pharmacies in the area.

   c) Customer is routinely filling prescriptions for controls written by one or more practitioners that are outside of a reasonable or justifiable radius from the pharmacy, e.g., more than 10 – 20 miles. **Note**: Requires review of the location of the prescriber relative to the location of the patient. If the doctor is a specialist in a particular medical field this may explain why the doctor is located a significant distance from the pharmacy or the patient. Some patients may need to travel farther to find a specialist as opposed to a pharmacy. We do not routinely ask for prescriber information, but when provided to us by the customer we do consider it.

2. Pharmacy's Business Model

   a) Ownership or Conflicts of Interest:

[2] Centers for Disease Control and Prevention: Vital Signs, "*Opioid Painkiller Prescribing, Where You Live Makes a Difference*", July 2014. http://www.cdc.gov/vitalsigns/opioid-prescribing/ accessed January 9, 2015.

i. The pharmacy's business model caters to one or more specific doctors that also have an ownership interest in the pharmacy.

ii. There has been a questionable change in ownership, e.g., sale of pharmacy to spouse or family member after disciplinary action.

b) Other than using the internet for scheduling refills, the pharmacy's business model includes receiving prescriptions for or dispensing controlled substances via the internet.[3]

c) Pharmacy services a clinic that is both a pain management clinic and a weight loss clinic.

d) There is a pain clinic located inside of or as part of the pharmacy.

e) Pharmacy owner, PIC, or other pharmacy employee demonstrates a lack of understanding of, or disregard towards exercising their corresponding responsibilities.

3. Governmental Information/Inquiry

a) Inquiry/Subpoena by government agency regarding customer.

4. Integrity Concerns

The general focus or concern from any disciplinary action should center on controlled substance matters or fraud as opposed to disciplinary actions that are simply administrative in nature. Attention should also be given to whether the customer exhibits a pattern of disciplinary action.

a) Invalid/inaccurate/inconsistent answers on questionnaire(s).

b) Failing to report thefts/losses.

c) Any discipline of state pharmacy license.

d) Previous suspension, revocation, memorandum of agreement or other disciplinary action related to the customer's DEA registration or previous registration.

e) Discipline of any pharmacy employee by a state licensing authority or other regulatory agency within the past 10 years.

f) Discipline of the pharmacy or any pharmacy employee by State Controlled Substance Authority.

[3] The Ryan Haight Act that took effect in April 2009 defines an "online pharmacy" (See 21 U.S.C. §802 (52)) and sets forth various requirements (See 21 U.S.C. §831). DEA registrants who meet the definition of an "online pharmacy" must have a modified DEA registration to reflect such activity. (See 21 C.F.R. §1304.40).

g) Restriction by Health and Human Services Office of Inspector General Exclusions Database. http://exclusions.oig.hhs.gov/ .

5. Other Distributors

a) Pharmacy purchases controlled substances from other distributors. **Note:** It is not uncommon for a pharmacy to have a secondary supplier to assist in meeting legitimate inventory needs. As a benchmark, our standard prime vendor business model allows for 10% of supply to be obtained from a secondary supplier. However, customer commitments can vary and should be factored into the evaluations.

b) Other distributors have restricted or ceased selling controls to the customer or potential customer in the past 5 years.

6. Manufacturer Inquiry

a) One or more manufacturers have inquired about the customer.

b) One or more manufacturers have restricted "charge-backs" to customer.

Statistical "Red Flags"

Statistical "red flags" may be uncovered when reviewing the customer's purchasing data or dispensing data while processing a threshold change request, conducting an onboarding assessment, conducting a proactive review, or conducting an event-triggered review. The following are some examples:

1. Solver data and/or Standard Deviation Calculator tool

a) A customer's controls/Rx ratio, when compared to similar customers serviced by the same distribution center, seems unusually high. (As a benchmark, DEA has previously stated that an average retail pharmacy's controls/Rx ratio is approximately 20 – 25%).

b) A customer's purchases for a particular base code exceed three standard deviations from the mean for the customer's servicing distribution center. This data may need to be combined with other data to reveal the significance of the red flag. For example: In addition to the customer's purchasing volume for a specific base code, is the population of the surrounding area substantial enough to support that volume?[4]

c) Customer's purchases are focused on only a couple base codes, such as oxycodone or hydrocodone, or the purchases focus specifically on the more abused strength for a particular base code, e.g. 30mg oxycodone or 10mg hydrocodone. For example, if the

[4] Population data can be found at http://www.census.gov/quickfacts/.

customer is only purchasing oxycodone or only oxycodone 30mg and no other strengths of oxycodone this would be an area of concern.

d) When compared against other customers from the same distribution center, the customer's purchases reflect a propensity towards the three base codes indicative of the "trinity" which include an opioid, a benzodiazepine, and a muscle relaxant, e.g. hydrocodone, carisoprodol, and alprazolam or the "holy trinity" oxycodone, carisoprodol, and alprazolam.

e) Customer's growth appears to center around controls without justification. A review over multiple quarters shows a continual climb in controls or specific base codes with little or no climb in non-controls.

f) Customer's total purchasing volume for controls is significantly higher when compared to other customers serviced by the same distribution center.

g) The customer's purchase data reflects that McKesson is not the primary distributor as they are purchasing only controlled substances and/or the customer is purchasing only limited base codes. (See 5(a) above in Non-Statistical Red Flags).

2. Dispensing Data:

a) The customer's dispensing data reflects that they are purchasing additional quantities of one or more base codes elsewhere and the cumulative volume exceeds their established threshold for the same base code(s).

b) The customer's script data shows that they fill a high volume of controlled scripts compared to a low volume of non-controls scripts. (As a benchmark, DEA has previously stated that an average retail pharmacy's controls/Rx ratio is approximately 20 – 25%.)

c) The customer's script data shows a high volume of scripts being filled for one specific base code.

d) The customer's dispensing data does not align with their purchasing data. For example, the customer is purchasing 40,000 per month of a particular base code, but their dispensing data reflects that they are only dispending 10,000 per month.

e) The total volume of controlled scripts or overall controlled dispensing is inconsistent with the population size for the location of the customer's business, especially when compared to other pharmacies in the immediate area.

Resources

The following is a list of resources to help keep abreast of diversion trends, prescription drug abuse, and other related topics.

1) White House Office of National Drug Control Policy: http://www.whitehouse.gov/ondcp

2) U.S. Drug Enforcement Administration: http://www.dea.gov/index.shtml and http://www.deadiversion.usdoj.gov/

3) Centers for Disease Control and Prevention: http://www.cdc.gov/

4) Substance Abuse and Mental Health Services Administration: http://www.samhsa.gov/

5) National Institute on Drug Abuse: http://www.drugabuse.gov/

6) U.S. Food and Drug Administration: http://www.fda.gov/

7) National Association of Boards of Pharmacy: http://www.nabp.net/

8) National Association of State Controlled Substance Authorities: http://www.nascsa.org/

9) National Alliance for Model State Drug Laws: http://www.namsdl.org/

10) Erowid: https://www.erowid.org/

11) Healthcare Distribution Management Association (HDMA): http://www.healthcaredistribution.org/.